

Notice of Allowability

Application No.

09/550,103

Examiner

Sandra Wegert

Applicant(s)

DETH, RICHARD C.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/20/03.
2. ☒ The allowed claim(s) is/are 5-9 (renumbered as 1-50).
3. ☒ The drawings filed on 14 April 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

The affidavit under 37 CFR 1.132, filed 23 October 2003, is sufficient to overcome the rejection of Claims 5-9 based upon 35 USC 112, first paragraph.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Holliday Heine on 23 March 2004.

The application has been amended as follows:

Claims 1-4 have been canceled without prejudice.

The application has been amended as follows:

Please replace Claim 5 with the following:

5. (Currently Amended) A method of identifying an agent for treating schizophrenia or a related neuropsychiatric disorder wherein said related neuropsychiatric disorder has the feature of involving modification of dopamine D4 receptor-linked phospholipid methylation and wherein said method comprises the steps of:

(a) establishing an assay system comprising a cultured cell line, said cultured cell line either naturally expressing D4 receptors or transfected with the D4 receptor gene;

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- (b) making an initial determination of the level of phospholipid methylation in cells of said cell line;
- (c) administering to cells of said cell line the candidate agent to be assessed;
- (d) making a subsequent determination of the level of phospholipid methylation in cells of said cell line; and
- (e) comparing the corresponding levels of phospholipid methylation from steps (b) and (d), wherein an increase in the level of phospholipid methylation subsequent to administration of the candidate agent indicates that the agent is potentially therapeutically effective for treating schizophrenia or said related neuropsychiatric disorder.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The Invention of the instant Application is a method of identifying therapeutic agents useful for the treatment of schizophrenia or related neuropsychiatric disorders, by using cultured cell lines transfected with the D4 dopamine receptor gene or by using naturally-occurring cells, such as lymphocytes, comprising the D4 receptor (see, for example: Sharma, et al., 1999, Mol. Psychiatry, 4:235-246.). The Specification describes the relationship between the D4 receptor and phospholipid methylation in cells comprising the receptor. Agents identified by the methods described would be expected to increase the amount of phospholipid methylation to normal levels. The claims are free of the prior art as the method has not been described

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previously, except in the Patent from which the instant Application claims priority (US Patent 6,080,549). The specification provides experimental evidence of utility and enablement under 35 U.S.C. 112, first paragraph. The claims also meet 35 U.S.C. 112- second paragraph requirements because the claims point out and distinctly claim the invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

23 March 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER